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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,845	08/06/2003	Hiraku Murayama	011350-316	6514
21839 7590 07/11/2007 BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER HOEKSTRA, JEFFREY GERBEN	
			ART UNIT 3736	PAPER NUMBER
			MAIL DATE 07/11/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/634,845

Applicant(s)

MURAYAMA ET AL.

Examiner

Jeffrey G. Hoekstra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,7-15,17-31 and 36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,7-15,17-31 and 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Notice of Amendment***

1. In response to the amendment filed on 04/18/2007, amended claim(s) 1 and 3, canceled claim(s) 2, 5, 6, and 32-35, and new claim(s) 36 is/are acknowledged. The current rejections of the claim(s) 1, 3, 7-15, and 17-31 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:
2. The Examiner notes the amendment filed on 04/18/2007 appears to be noncompliant for failing to properly identify the status of claims 30 and 31 as (Previously Presented) rather than (New). However, in the interest of continued prosecution the Examiner is treating them as such.

### ***Claim Objections***

3. Claims 1 and 3 are objected to because of the following informalities: the term "substantially" is a relative term that appears to render the claim(s) indefinite. The term "substantially" is not defined by the claim(s), the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The degree of heating versus non-heating of the wire member upon application of the cover layer is unclear. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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5. Claims 1, 3, 7-10, 12-13, 17-20, 22-24, 26-28, 30-31, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Uchino et al (US 6,001,068) as broadly as *structurally* claimed.

6. For claims 1, 3, 9, 10, 26, and 36, Uchino et al discloses a guidewire member (1, 10, 51, 80, 90, or 100), comprising:

- a first distal wire member (A or 61) having a proximal end face butt resistance welded to a second proximal wire member (B or 62) having a distal end face, wherein said first distal wire's proximal end face is butt resistance welded to said second proximal wire's distal end face (as best seen in Figures 3(3), 8, and 9 and column 8 lines 16-19 and column 11 line 11 – column 14 line 67) without axial overlap of said first and second wires, creating a welded portion;
- a cover layer (12 or 63) provided on the outer periphery that uniformly covers said welded portion (as best seen in Figure 9), wherein said cover layer can be made of a metal with an elastic modulus that is less than that of said first wire (column 3 line 37 – column 4 line 65 and column 11 line 11 – column 14 line 67) or a silicon resin (column 6 lines 19-65 and column 11 line 11 – column 14 line 67); and
- a distal-side cover layer (67, 81, or 113) disposed distally from said cover layer (as best seen in Figure 9), made from a different material (and column 11 line 11 – column 14 line 67), and not overlapping said cover layer (as best seen in Figure 9),
- wherein said cover layer is capable of being formed in a manner such that the wire member is substantially not heated at a time of covering the wire member with the cover layer (column 11 line 11 – column 14 line 67), and

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- wherein the distal-side cover layer is capable of being formed in a manner such that the wire member is heated at a time of covering the wire member with the distal-side cover layer (column 11 line 11 – column 14 line 67).

7. For claims 7-10, 12-13, 17-20, 22-23, and 27-28, Uchino et al discloses said cover layer and said distal-side cover layer being hydrophilic and reducing friction (column 12 lines 47-56).

8. For claims 14, 24, 30 and 31, Uchino et al discloses a composite guidewire comprising different wire materials including: said distal wire being a superelastic alloy wires and said proximal wire being stainless steel (column 3 line 37 – column 4 line 65 and column 11 line 11 – column 14 line 67).

***Claim Rejections - 35 USC § 103***

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 11, 21, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchino et al. Uchino et al discloses the claimed invention but does not disclose expressly the thickness of the cover layer and distal-side cover layer being 1 micron. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the guidewire as taught by Uchino et al with the thickness of the cover layer and distal-side cover layer being 1 micron, because Applicant has not disclosed that Uchino et al provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the thickness of the metallic layer

(column 12 lines 24-25) as taught by Uchino et al, because it provides for connecting unlike materials when configuring a guidewire with varying mechanical properties and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Uchino et al. Therefore, it would have been an obvious matter of design choice to modify Uchino et al to obtain the invention as specified in the claim(s).

11. Claims 15 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchino et al in view of Reynolds et al (US 2003/0069521 A1). Uchino et al discloses the claimed guidewire as aforementioned except for explicitly disclosing the use of Co-Ni-Cr based alloy wire. Reynolds et al teaches the use of cobalt-based alloys in guidewire construction (paragraph 33). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the composite guidewire as taught by Uchino et al, with the Co-Ni-Cr based alloy wire as taught by Reynolds et al for the purpose of coupling wires having varying mechanical properties to configure the guidewire for traversing tortuous vasculature.

### ***Response to Arguments***

12. Applicant's arguments with respect to claims 1, 3, 7-15, 17-31, and 36 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571) 272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./

Jeff Hoekstra

Examiner, Art Unit 3736

  
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